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| APPLICATION NO.                                                                                                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/563,148                                                                                                        | 01/04/2006  | Yorio Tanaka         | 050820              | 1150             |
| 23850 7590 09/18/2008<br>KRATZ, QUINTOS & HANSON, LLP<br>1420 K Street, N.W.<br>Suite 400<br>WASHINGTON, DC 20005 |             |                      |                     |                  |
| EXAMINER                                                                                                          |             |                      |                     |                  |
| BADR, HAMID R                                                                                                     |             |                      |                     |                  |
| ART UNIT                                                                                                          |             | PAPER NUMBER         |                     |                  |
| 1794                                                                                                              |             |                      |                     |                  |
| MAIL DATE                                                                                                         |             | DELIVERY MODE        |                     |                  |
| 09/18/2008                                                                                                        |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/563,148

## Applicant(s)

TANAKA, YORIO

## Examiner

HAMID R. BADR

## Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date 01/04/2006, 5/08/2007

## **DETAILED ACTION**

### ***Objection to Specification***

1. Abstract of the disclosure is objected to for being confusing. The first sentence of the abstract " Freezing of raw yeast before processing enables not only ingestion of nucleic acids live to thereby realized maximum utilization of nucleic acid effects but also maintaining cell freshness". This sentence is confusing. Correction is required.
2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: on page 4 of the specification, the last paragraph reads: "In the solution as described above, the ribonucleic acid among the nucleic acids combined with the aqueous solution of a pineapple enzyme having an enzymatic function is capable of enhancing co-enzymatic functions". This sentence is confusing and improperly written. Further, on page 5, the first paragraph is confusing.

### ***Objection to Drawings***

1. Fig. 2, Fig 3 and Fig. 4 are objected to for inaccurate titles and/or data. Fig. 2, has inaccurate title and data. Title is confusing and inaccurate. It is not clear what is meant by "in the case of 0.5 g". On the other hand if the table is supposed to show the percentages of components, two components can not be at 99%. Correction is required.

In Fig. 3, the title indicates the composition of pineapple enzyme and the table depicts live yeast and citric acid. "in the case of 7000 fold dilution" is also confusing. Correction is required.

In Fig. 4, the title is incorrect. "Propagation of yeast a contaminated water (sludge)" is not descriptive for the data in the table. The title should be revised. The data in Fig. 4 is not descriptive. The terms used in the table are not self explanatory. The table should be fully revised.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Freezing and thawing to make cell free extract and using proteolytic enzymes at high temperature (60C as presently claimed) will bring about the death of microbial cells (yeast cells as presently claimed). Therefore, production of a solution containing "live yeast" as presently claimed is not enabling.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1-9 are indefinite for "a live yeast". The claim as stated is confusing. It is not clear what is meant by "a live yeast".
6. Claim 5-8 are indefinite for production of "the live yeast containing solution" and "collecting the supernatant". Since the word "supernatant" is known in the art to be indicative of a cell free extract, the phrase "the live yeast containing solution" makes the claim confusing and contradictory.
7. Claim 9 is indefinite for "a sweetener such as sugar or honey". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86

USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation sweetener, and the claim also recites sugar or honey which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chao et al. (US 4,218,481; hereinafter R1) in view of Kinast et al. (US 4,266,025; hereinafter R2) or Liesch et al. (US 5,728,549; hereinafter R3).

10. R1 discloses a process for the preparation of yeast autolyzate by adding to an aqueous slurry of active yeast cells at least one enzyme selected from the group consisting of papain, ficin, bromelain etc. and maintaining the slurry containing the added enzymes at a temperature of about 40-60C for about 2-24 hours with continuous mixing to yield an autolyzed yeast slurry. (Col. 3, lines 57-66).

11. R1 discloses that the resulting processed slurry can be clarified by centrifugation and spray dried to give a yeast autolyzate. If a yeast autolyzate is desired, the processed yeast slurry can be centrifuged to remove the cell debris, leaving a supernatant which contains solubilized materials. (Col. 4, lines 3-16)

12. R1 teaches of using the most effective enzymes in aiding the yeast autolysis including papain, ficin and bromelain. The optimal pH for such enzymes is about 5.0-6.5 (Col. 5, lines 11 and 19).

13. Given that bromelain is an effective enzyme for aiding yeast disintegration, and knowing that pineapple contains bromelain as a proteolytic enzyme, it would be obvious to one of ordinary skill in the art to use pineapple juice to effectuate the proteolysis of yeast cells.

14. R1 is silent regarding the cell disintegration and cell free extract preparation.

15. R2 discloses that cell free extracts can be prepared by conventional disintegration of microorganisms such as ultra sonic treatment, passage through a French pressure cell, grinding with quartz, incubation with lysing enzymes, autolysis or repeated freezing and thawing. (Col. 7, lines 20-26).

16. Alternatively, R3 discloses the disintegration process for bacteria by alternately freezing the suspension in liquid nitrogen and thawing it. This operation is repeated 5 times (Example 21).

17. The freezing/thawing cycles to break down the microbial cell walls is a well known process in the art as disclosed by R2 or R3. Cell free extracts are prepared by freezing the cell mass at about -70C and thawing at much higher temperatures. Thawing at refrigeration temperatures as presently claimed will help prevent microbial spoilage of the yeast mass. Such freezing/thawing cycles can be repeated depending on the microbial species involved. Cutting the chunks of cell mass is considered another physical means of disrupting and disintegrating the cells. This physical means

of disrupting cells can only be done on frozen cell mass since cutting can not affect thawed liquid cell mass. Therefore, limitations of claims 2-3 are obvious to those of skill in the art. The freeze/cutting/thawing process is done to facilitate the cell lysis. This is done for breaking the cell walls as well as exposing more cell surfaces to the proteolytic enzymes for the preparation of cell extracts.

18. Diluting pineapple pieces with water to make pineapple juice or punch is also known in the art. Water for dilution can be potable water including degassed water or deep ocean water as presently claimed.

19. Regarding claims 7-8, it is obvious that ratio of yeast to pineapple juice can be changed to make various compositions. A composition at a higher concentration of the yeast component will provide more cellular components such as enzymes and nucleotides. At a higher concentration of pineapple juice, more plant components such as enzymes will be provided. Therefore to have various doses of cellular components or the plant components, one would make combinations at different ratios.

20. Although R1 does not disclose process of claims 5-8 regarding making the solution of pineapple enzyme, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . Further, "although produced by a different process, the burden shifts



to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed process and given that R1 meets the requirements of the claimed composition, R1 clearly meet the requirements of present claims 5-8.

21. Addition of citric acid and sweetener as presently claimed would help improve the taste or the beverage (solution). Citric acid will also help adjust the pH of the solution for the action of the proteolytic enzyme of pineapple juice. R1 teaches that the optimum pH would be in the 5.0-6.5 range.

22. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to prepare cell free extracts of yeast by using enzymes contained in pineapple juice and adopting the freeze/thaw technique already known in the art. One would do so to prepare yeast autolyzates useful for various purposes. Absent any evidence to contrary and based on the combined teachings of the references cited, there would be a reasonable expectation of success to prepare yeast autolyzate.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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